

REMARKS

This Amendment is responsive to the Office Action mailed July 1, 2008. With this Amendment, claims 1, 6-9, and 11 have been amended; claim 13 has been added; and claim 5 has been cancelled. Claims 2-3, 10, and 12 are deemed withdrawn, as directed to a non-elected invention. Claims 1-4 and 6-13 are pending. Applicants submit that new claim 13 is examinable with the elected subject matter.

Support for the amendment can be found throughout the specification and claims as filed, including, e.g., at page 5, paragraphs [0022]-[0023]; page 3, paragraph [0010]; and original claim 5.

Election/Restriction

Applicants thank the Examiner for reconsideration of the requirement for election/restriction set forth in the paper mailed February 4, 2008. Applicants note that the restriction requirement holding Group I (claims 1, 4-9, and 11) to be under prosecution has been made final. Applicants further note that the Examiner has withdrawn claims 2, 3, 10, and 12 from consideration. The withdrawn claims remain pending, as they are subject to possible rejoinder.

Information Disclosure Statement

Applicants thank the Examiner for acknowledgement of receipt of the Information Disclosure Statements filed November 14, 2006 and April 16, 2007. In addition, Applicants thank the Examiner for consideration of all the documents listed therein (with the exception of

two foreign patent documents which were lined through), as indicated by the Examiner's electronic signature.

However, the Office Action does not indicate consideration of the Supplemental Information Disclosure Statement filed July 17, 2008. Applicants therefore respectfully request the Examiner to consider the documents submitted on July 17, 2008, as well as the Information Disclosure Statement submitted herewith, which includes the two foreign patent documents previously lined through, and to indicate such consideration with the next official communication.

Specification

The Office Action objects to the specification because the clean copy of the abstract submitted on July 14, 2006 does not match the abstract from the WIPO document, WO 2005/068631.

In response, Applicants submit herewith an Abstract that is reflective of the invention under consideration by the Office.

The Office Action has also noted the use of the trademark SILWET L-77.

In response, Applicants submit that the instant Amendment is fully responsive to the objections to the specification and respectfully request withdrawal of the same. In particular, Applicants note that the trade name SILWET L-77 has been capitalized and that the generic terminology for SILWET L-77 has been inserted into the specification as suggested by the Examiner. Applicants note that the insertion of the generic terminology does not constitute new

matter because the generic terminology was known at the time of filing of the present application, e.g., as described in U.S. Patent No. 5,906,961 at column 4, lines 48-49.

Claim Objections

The Office Action objects to claim 1 for informalities, and to claims 7-9 and 11 for utilization of an improper article for a dependent claim.

In response, Applicants respectfully submit that the present Amendment addresses the instant objections, and respectfully request withdrawal of the same.

Claim Rejections – 35 U.S.C. § 101

The Office Action rejects claims 1 and 4-6 under 35 U.S.C. § 101, as allegedly directed to non-statutory subject matter. In particular, the Office Action alleges that the claimed product as written reads on a naturally occurring molecule that occurs in a wild-type *Arabidopsis* plant.

In response, Applicants respectfully submit that the present Amendment addresses the instant rejection, and respectfully request withdrawal of the rejection. Specifically, Applicants have amended claim 1 to recite in part “An isolated polynucleotide...” as suggested by the Examiner, and have cancelled claim 5.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Office Action rejects claims 1, 4-9, and 11 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for recitation of “gene” in claims 1 and 6.

In response, and without acquiescing to the propriety of the rejection, Applicants have amended claims 1 and 6 to be even clearer and more definite. Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office Action rejects claims 1, 4-9, and 11 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement and as allegedly claiming subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Action alleges that Applicants (1) do not describe any DNAs ‘derived from’ SEQ ID NO: 1 that function as an IRES, and (2) do not describe SEQ ID NO:1 as having IRES activity in any plant other than *Arabidopsis*.

In response, Applicants submit that the claimed subject matter is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Furthermore, and while not acquiescing to the propriety of any of the assertions made in the rejection of the claims under 35 U.S.C. § 112 (written description), Applicants respectfully submit that the present amendment addresses the instant rejection and respectfully request withdrawal of the same.

In particular, Applicants submit that the specification fully describes the claimed subject matter. For example, in addition to the disclosure of SEQ ID NO: 1, the instant specification discloses the complete nucleotide sequences of sixteen variants of SEQ ID NO: 1 (see SEQ ID

NOs: 5-20, and paragraph [0024] on page 6). Paragraph [0023] on page 5, and paragraph [0025] on pages 6-7, further provide guidance with regard to the nucleotide substitutions which can be made to SEQ ID NO: 1, and describe how the disclosed variants of SEQ ID NO:1 relate to 18s rDNA from various different plants. Figure 1 also discloses the given regions serving as sources for designing the nucleotide sequences of SEQ ID NOS: 1 and 5 to 20, as indicated by "R." In addition, the specification describes methods for producing the polynucleotides of the instant invention and for introducing a desired mutation into nucleotide sequences (see, e.g. page 8, paragraph [0028]).

With regard to the plant species encompassed by the claims, paragraph [0055] on page 15 describes examples of the plants that can be transformed with the claimed polynucleotides, including plants belonging to the families *Brassicaceae*, *Poaceae*, *Solanaceae*, and *Leguminosae*. Paragraph [0056] bridging pages 15-16 also describes specific examples of plants belonging to various families for use with the claimed IRES. Thus, the specification provides written description support of the disclosed and claimed genus, including a sufficient number of representative species of the genus and sufficient recitation of physical, structural, chemical, and functional properties of the claimed subject matter.

Based at least on the foregoing, Applicants submit that the claimed subject matter was described in the specification in such a way as to convey to those skilled in the art that Applicants were in possession of the claimed invention at the time of filing. Therefore, Applicants respectfully request reconsideration and withdrawal of the written description rejection under 35 U.S.C. §112, first paragraph.

The Office Action also rejects claims 1, 4-9, and 11 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Action alleges that that the specification, while being enabling for a polynucleotide comprising 10 repeats of SEQ ID NO: 1 that functions as an IRES in *Arabidopsis*, and a vector comprising said polynucleotide and a transformed *Arabidopsis* plant comprising said polynucleotide, does not reasonably provide enablement for a polynucleotide comprising “a” DNA of SEQ ID NO: 1 or a DNA “derived from” SEQ ID NO: 1, or for IRES activity in any plant other than *Arabidopsis*. In particular, the Action alleges the use of the article “a” in front of “DNA of the nucleotide sequence represented by SEQ ID NO: 1” renders the claim inclusive of fragments of SEQ ID NO: 1 as small as dinucleotides (see Office Action at page 10, first full paragraph). Furthermore, the Office Action alleges that the state of the art is such that “one of skill in the art cannot predict which species of plants a nucleic acid will function as an IRES in” (see page 11, second full paragraph). The Office Action also alleges that given the lack of guidance in the specification, one of ordinary skill in the art would be required to engage in “undue trial and error experimentation” (see Office Action at page 12, first full paragraph).

In response, Applicants submit that the specification provides sufficient guidance such that one of skill in the art could make and use the claimed invention without undue experimentation. Furthermore, and while not acquiescing to the propriety of any of the assertions made in the rejection of the claims under 35 U.S.C. § 112 (enablement), Applicants respectfully submit that the amendment addresses the instant rejection and respectfully request withdrawal of the same. Applicants have, for example, amended claim 1 to recite “[a]n isolated polynucleotide which functions as an IRES (internal ribosome entry site) in a plant and comprises seven to ten repeats of the following DNA (a) or (b):

(a) DNA of the nucleotide sequence represented by SEQ ID NO: 1; or

(b) DNA of a nucleotide sequence derived from the nucleotide sequence represented by SEQ ID NO: 1 by the substitution, deletion, addition, and insertion of two to five bases and having a function of positively regulating the translation of a nucleic acid located downstream thereof.” Thus, e.g., the nucleic acid sequences encompassed by claim 1 would not comprise a genus of nucleic acids which encompasses fragments of SEQ ID NO: 1 as small as dinucleotides.

Applicants further submit that whether or not an Applicant’s invention is enabled has been determined by the courts to involve several factors including the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicants submit that the specification provides sufficient guidance with respect to the encompassed sequences, such that one of ordinary skill in the art could make and use the invention without undue experimentation. Applicants further assert that the skill level of one of ordinary skill in this particular art is high, and that one of ordinary skill in the art would know, based on the instant disclosure, nucleic acid sequences involved in positively regulating the translation of coding regions located downstream.

Applicants wish to emphasize that the disclosure provides the detailed sequence structure for exemplary nucleic acids encompassed by the claims. Indeed, the specification indicates

particular nucleotides, which can be modified and still retain IRES function (see SEQ ID NOs: 5-20, and paragraph [0024] on page 6).

The claimed invention is also enabled for at least the reasons set forth in Applicants' response to the rejection of the claims under 35 U.S.C. § 112, first paragraph (written description), e.g., the specification (1) describes methods for producing the polynucleotides of the instant invention and for introducing a desired mutation into nucleotide sequences (see, e.g. page 8, paragraph [0028]); (2) provides guidance with regard to the nucleotide substitutions which can be made to SEQ ID NO: 1 (paragraph [0023] on page 5); and (3) describes how the disclosed variants of SEQ ID NO:1 relate 18s rDNA from various different plants (paragraph [0025] on pages 6-7).

Based on at least the foregoing, Applicants submit that the instant disclosure provides clear and sufficient guidance such that the claimed invention is enabled. Applicants respectfully request reconsideration and withdrawal of the rejections under the enablement requirement of 35 U.S.C. §112, first paragraph.

Claim Rejections – 35 U.S.C. §102(b)

The Office Action rejects claims 1, 4-6, 8, and 9 under 35 U.S.C. § 102(b) as allegedly anticipated by Alonso et al. (GenBank Accession No. BH789726 (2002); hereinafter "ALONSO"). The Office Action also rejects claims 1, 4-9, and 11 under 35 U.S.C. §§ 102(a) and 102(e) as being anticipated by La Rosa (U.S. Patent Application Publication No. 2004/0031072; hereinafter "LA ROSA"). The Office Action also rejects claims 1, 4-9, and 11

under 35 U.S.C. § 102(b) as being anticipated by Akbergenov et al. (*Nucleic Acids Research* **32**:239-247, 2004; hereinafter "AKBERGENOV").

In response, Applicants submit that the claims as amended are not anticipated by ALONSO, LA ROSA, or AKBERGENOV. In particular, Applicants submit that neither ALONSO, LA ROSA nor AKBERGENOV disclose "[a]n isolated polynucleotide which functions as an IRES (internal ribosome entry site) in a plant and comprises seven to ten repeats of the following DNA (a) or (b):

(a) DNA of the nucleotide sequence represented by SEQ ID NO: 1; or

(b) DNA of a nucleotide sequence derived from the nucleotide sequence represented by SEQ ID NO: 1 by the substitution, deletion, addition, and insertion of two to five bases and having a function of positively regulating the translation of a nucleic acid located downstream thereof."

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(a), (e), and (b).

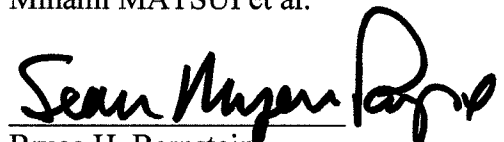
CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow all the pending claims.

No additional fee is believed due at this time. If, however, any additional fee is necessary to ensure consideration of the submitted materials, the Patent and Trademark Office is hereby authorized to charge the same to Deposit Account No. 19-0089.

Any comments or questions concerning this application can be directed to the undersigned at the telephone number given below.

Respectfully Submitted,
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